

# FACT SHEET: The Federal Regulatory Landscape of AI in Health Care

Artificial intelligence (AI) is a major area of focus for stakeholders across the health care ecosystem – such as patient advocates, tech innovators, health systems, and policymakers. AI has the potential to augment patient care and reduce administrative workloads for providers, but without proper guardrails, there are also inherent risks for patient outcomes, data privacy, and health inequities. While the technology itself evolves and integrates into everyday people’s health care experiences, so too does the surrounding policy landscape, with the federal government starting to take action on the growing use of AI in health care.

The term “artificial intelligence” is used in a variety of contexts and has many different definitions, even across regulatory bodies. While the use of AI in health care dates back to the 1950s, the technology has developed into increasingly more complex algorithms in the last decade, capable of making decisions and responding to the information fed into the models by users. USofCare believes that future policy efforts to regulate AI must be inclusive of all forms and types of this technology.

## Predictive vs. Generative AI

Predictive AI makes predictions based on the existing data fed to it. It has long been used in health care, going back to the early applications of the technology. Medical algorithms have been relied upon for years to assess patients for increased risk of certain conditions when given data like health history, lifestyle habits, and genetic makeup. Generative AI is a newer technology that has emerged over the last decade, hence why it is a growing area of interest for policymakers and stakeholders. These models have the ability to continue learning from datasets, which trains them to improve upon interactions with patients and establish a feedback loop with health care providers. Generative AI generates outputs (e.g. text, images, videos) based on the existing data fed to it, which it may or may not fold back into as data in the model. Up to this point, it has mostly been applied to augment two major areas of health care: provider administrative workflow and diagnostic processes.

## Administrative Actions

The White House released an Executive Blueprint for an AI Bill of Rights in October 2022, with five principles to guide the design, use, and deployment of automated systems:

**Safe and Effective Systems:** Automated systems will undergo “pre-deployment testing, risk mitigation, and ongoing monitoring” to assess whether a system is faulty, not working as intended, or explicitly seeks to violate individual safety and privacy.

**Algorithmic Discrimination Protection:** Automated systems risk perpetuating discriminatory practices in their judgements if there are no guardrails in place to ensure the design of more equitable algorithms.

**Data Privacy:** This principle concerns automated systems’ abilities to access, collect, use, transfer, and/or delete user data without knowing consent. The current practices must be reformed so that terms and conditions surrounding request for data access permissions should be brief and transparent.

**Notice and Explanation:** Continuing in the same vein of AI transparency, the Notice and Explanation principle stipulates that “designers, developers, and deployers of automated systems should provide generally accessible plain language documentation” of the hows and whys AI is being implemented in a service.

**Human Alternatives, Considerations, and Fallbacks:** Users should be granted the opportunity to opt out of automated services in favor of human alternatives.

The White House followed this Blueprint with an October 2023 Executive Order on the Safe, Secure, and Trustworthy Development & Use of Artificial Intelligence (Executive Order 14110). This AI Executive Order called for sweeping protections for patients interacting with AI in health care systems, as well as calling for explicit guidelines to prevent and mitigate harm from algorithmic bias.

## Agency Task Forces

The Department of Health and Human Services (HHS) AI Task Force was created via Executive Order 14110. The goal is to develop a comprehensive federal strategy towards the core issues surrounding AI: drugs and devices; research and discovery; critical infrastructure; biosecurity; public health; health care and human services; internal operations; and ethics and responsibility. Additionally, many high-ranking HHS officials – including staff from CMS, ONC, OCR, CDC, and the FDA – are members of the Coalition for Health AI (CHA), a cross-stakeholder coalition convening to develop “guidelines and guardrails” for fair and transparent AI to promote high-quality health care.

## Regulatory Actions within HHS

The White House has put HHS broadly in charge of overseeing the federal landscape of AI in health care. The various HHS sub-agencies are undertaking investigations within their individual domains of regulation and research, with notable efforts (as of the time of publication) including, but not limited to:

Subagency	Action
Administration for Children & Families (ACF)	The ACF published a <u>report</u> in early 2023 on “emerging issues and needs” around AI in the health and human services sectors.
Administration for Strategic Preparedness & Response (ASPR)	ASPR is <u>utilizing AI</u> to improve COVID-19 data collection, analysis, and forecasting, as well as the distribution of and access to vaccines.
Agency for Healthcare Research & Quality (AHRQ)	AHRQ published a <u>conceptual framework</u> in December 2023 to address the applications of AI in health care and the necessity of identifying and filtering out AI biases to achieve greater health equity.
Centers for Disease Control & Prevention (CDC)	The CDC is <u>using AI</u> to estimate suicide fatalities, forecast opioid overdose mortality trends, and other sentinel public health events.
Centers for Medicare & Medicaid Services (CMS)	CMS issued a <u>Final Rule</u> in April 2023 requiring Medicare Advantage organizations to make medical necessity determinations based on an individual’s circumstances, rather than relying on algorithmic judgment.
Food & Drug Administration (FDA)	In May 2023, the FDA issued a <u>discussion paper</u> seeking guidance and feedback on navigating the new terrain of using AI-enabled devices to improve diagnosis and treatment processes, as well as expand patient access to care. The subagency has also <u>announced</u> its intent to publish guidelines for data quality, transparency, and standard definitions for the use of artificial intelligence in drug and device development by the end of 2024.
National Institutes of Health (NIH)	The NIH announced the <u>Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity</u> (AIM-AHEAD) program to address the current lack of diversity in AI/ML researchers and data and the risk these gaps pose for perpetuating existing medical biases and health inequities.
Office of Civil Rights (OCR)	The April 2024 <u>final rule</u> from the HHS Office for Civil Rights and the Centers for Medicare & Medicaid Services explicitly states that certain entities must take action to mitigate the risk of discrimination from the usage of AI tools in clinical decision making.
Office of the National Coordinator for Health Information Technology (ONC)	ONC finalized a <u>rule</u> in December 2023 to “advance health IT interoperability and algorithm transparency.”

## Congressional Actions & Task Forces

To date, Congressional interest on AI has generally increased, with several Members and staff coming to the issue ready to engage and learn how these technologies are embedded in everyday life for people, while understanding the unintended risks and consequences that AI could pose without policy guardrails and frameworks in place.

- ★ **House Digital Health Caucus:** Led by Representatives Troy Balderson (R-OH) and Robin Kelly (D-IL), the mission of the Caucus is to keep policymakers informed of the rapid advancements in digital health innovation, highlight the potential impacts on patients and the health care system, and ensure that all Americans benefit from emerging digital health tools.
- ★ **House Bipartisan Task Force on Artificial Intelligence:** House Speaker Mike Johnson (R-LA) and House Minority Leader Hakeem Jeffries (D-NY) appointed Representatives Jay Obernolte (R-CA) and Ted Lieu (D-CA) to lead the Task Force, which works to continue AI innovation in America while also establishing guardrails against new and developing threats.
- ★ **Senate Bipartisan AI Working Group:** After hosting nine insight forums with experts in Fall 2023, Senate Majority Leader Chuck Schumer (D-NY), Senator Mike Rounds (R-SD), Senator Martin Heinrich (D-NM), and Senator Todd Young (R-IN) unveiled their framework for future AI policy across a variety of sectors in May 2024. Their framework includes recommendations for future action to support innovation, streamline processes and reimbursement systems, and protect against fraud and abuse, but do not include any specific directives to center equity or the patient perspective in health care AI.